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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,963	07/26/2000	Hans Josef Stauss	ICI 101	8595

7590 11/03/2004

PATREA L. PABST  
PABST PATENT GROUP LLP  
400 COLONY SQUARE STE. 1200  
1201 PEACHTREE STREET  
ATLANTA,, GA 30361

EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/625,963

Applicant(s)

STAUSS ET AL.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 7, 15 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7, 15 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 04122004, 07302004
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

This application is a continuation of Application Serial Number PCT/GB99/03572.

Claims 2-4, 6, 8-14, 16-18, 20-48 have been canceled.

Claims 1, 5, 7, 15 and 19 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendment filed July 30, 2004 only the following ground of rejection is maintained.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 5, 7, 15 and 19 stand rejected under 35 U.S.C. 102(e) as being anticipated by the U.S. Patent Application Publication 20030082196 A1 (published May 1, 2003; on form PTO-892), which claims priority to U.S. Patent Application serial number 09/164,223; filed September 30, 1998.

It was previously stated: "The '196 publication teaches the RMFPNAPYL peptide of instant SEQ ID NO: 1 as an immunogenic fragment of the human WT1 polypeptide as SEQ ID NO: 185 and as a fragment of the murine WT1 polypeptide as SEQ ID NO: 293 (paragraph 0008 and claim 5 in particular). The '196 publication teaches that immunogenic peptides of WT1 can be formulated into a pharmaceutical composition or vaccine (paragraphs 0109-0111 in particular) that can be used to "prevent, delay or treat a disease associated with WT1 expression" (paragraph 0120 in particular). The aforementioned teachings are disclosed in the parent 09/164,223) application. Applicant should note that, while the front page of the '196 publication does not refer to the relationship to the '223 application, the first paragraph of the specification does properly claim priority to the '233 application in the first paragraph. The prior art teaching anticipates the claimed invention."

Applicant's arguments filed July 30, 2004 have been fully considered but they are not persuasive. Applicant contends that the '196 does not anticipate the claimed peptides, pharmaceutical composition and vaccine because the '196 does not teach that "the peptide is processed by HLA-A0201-positive antigen presenting cells" and the reference therefore does not teach every element of the claim as required by the statute. However, Applicant's asserted limitation merely constitutes a manner for obtaining the

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peptide, thereby claiming the peptide in a product-by-process fashion, relying upon an intracellular processing step to distinguish the final product. The patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claim (see *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985))." In the present case, the exact peptide, RMFPNAPYL, is taught by the '196 publication as an immunogenic fragment of WT1 and is the same as the instantly claimed peptide, irrespective of the manner of isolation or processing.

### *Conclusion*

2. Copies of the references cited on form PTO-892 are not included because they were supplied by Applicant. The references were cited in the response filed July 30, 2004, but the copies included with the response were not imaged. Accordingly, the present form PTO-892 has been entered solely to make the references of record.

3. No claim is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *RV*  
Patent Examiner  
October 25, 2004

*Patrick J. Nolan*  
PATRICK J. NOLAN, PH.D.  
PRIMARY EXAMINER

*10/26/04*